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Soil Column Leaching Studies

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16. Abstract (Limit: 200 words)

The Standard Evaluation Procedure for the Soil Column Leaching Studies is a guidance document primarily intended for Agency reviewers and the regulated industry who evaluate toxicologic effects data specified in 40 CFR Part 158.124. The SEP is also intended to provide information to the general public indicating how the Agency evaluates these types of studies. As such, it is designed to supplement Subdivision N of the Pesticide Assessment Guidelines - Chemistry: Environmental Fate.

The SEP for Soil Column Leaching Studies is only one of a number of SEP's published by the National Technical Information Service as a supplement to Subdivision N of the Pesticide Assessment Guidelines.

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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

SOIL COLUMN LEACHING STUDIES

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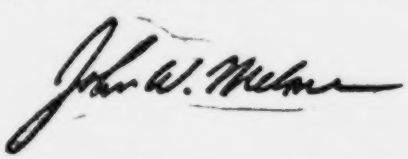
STANDARD EVALUATION PROCEDURE

PREAMBLE

This Standard Evaluation Procedure (SEP) is one of a set of guidance documents which explain the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs. The SEPs are designed to ensure comprehensive and consistent treatment of major scientific topics in these reviews and to provide interpretive policy guidance where appropriate. The Standard Evaluation Procedures will be used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. While the documents were developed to explain specifically the principles of scientific evaluation within the Office of Pesticide Programs, they may also be used by other offices in the Agency in the evaluation of studies and scientific data. The Standard Evaluation Procedures will also serve as valuable internal reference documents and will inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. I believe the SEPs will improve both the quality of science within EPA and, in conjunction with the Pesticide Assessment Guidelines, will lead to more effective use of both public and private resources.



John W. Melone, Director
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TABLE OF CONTENTS

	Page
I. INTRODUCTION	
A. Objective of the Standard Evaluation Procedure	1
B. General Theory of Leaching	1
II. THE SUBMITTED STUDY	
A. Purpose	1
B. Study Design	2
III. THE EVALUATION PROCESS	
A. Determine the Need for the Study	2
B. Read the Report	3
C. Prepare the Data Evaluation Record (DER)	3
1. Write the Technical Evaluation	4
2. Determine Study Acceptability	4
3. Determine the Need for Deferral/ Referral to Other HED Branches	5
4. Make Regulatory Determination	5
IV. APPENDICES	
Appendix 1: General Theory	6
Appendix 2: Information to be Included	8
Appendix 3: Analytical Data to be Submitted by the Registrant	13
Reference Citations	16

SOIL COLUMN LEACHING STUDIES

I. INTRODUCTION

A. Objective of the Standard Evaluation Procedure

This Standard Evaluation Procedure (SEP) is to be used as an aid for Exposure Assessment Branch data reviewers in their evaluations of the soil column leaching studies submitted by registrants in support of pesticide registration.

Leaching and sorption/desorption tests are required by 40 CFR §158.130 in support of registration of each active ingredient in manufacturing-use products and in the pesticide end-use products formulated and intended for domestic outdoor use, greenhouse use, terrestrial noncrop use, forestry use, aquatic use, and aquatic uses involving direct discharge of treated water into outdoor aquatic sites.

Section 163-1 in the Subdivision N Guidelines[1] describes this study and provides a protocol for conducting it. Subdivision N Guidelines list options available for fulfilling this requirement for terrestrial noncrop uses, orchard crop uses, field crops, field-vegetable crop uses, and forestry uses. The mobility of the test substance and its degradation products in soil may be assessed by soil thin layer chromatography (soil TLC), soil column, or batch equilibrium (adsorption/desorption) testing.

When considered with other data required by 40 CFR §158.130, data on the mobility of pesticides are used by the reviewer to determine (1) the leaching potential of pesticides and their degradates through the soil profile at terrestrial sites, and (2) the potential mobility of pesticides and their degradation products to and dispersion in aquatic sites. Such movement may result in loss of usable land and water resources to man due to contamination of groundwater supplies, or cause habitat loss to wildlife.

B. General Theory of Leaching

The reviewer should be acquainted with the soil-water processes in the soil influencing pesticide mobility. The reviewer is directed to Appendix 1 for a brief description of these processes.

II. THE SUBMITTED STUDY

A. Purpose

The soil column leaching tests provide information on

(1) the leaching potential of pesticides and their degradates through the soil profile at terrestrial sites, and (2) the movement of pesticides and their degradates to and dispersion in aquatic sites. The soil column leaching study provides an estimate of pesticide mobility in soil for both the test chemical (parent compound) and aged residues.* The leaching test with the parent compound isolates pesticide mobility from many of the interactions of chemical and biological transformations, plant uptake, variations in soil moisture and temperature, etc..[2] All of these can influence the amount and depth of the chemical leached in the natural environment.[2] However, the aged residue leaching test provides for the assessment of the leaching potential of the soil degradation products resulting from the chemical and biological transformation of the parent compound.

Information gained from the leaching test can be applied to the design and conduct of the field dissipation study. Results obtained will be an estimate of field movement,[3] and will alert the registrant as to the depth at which soil samples will have to be taken.

B. Study Design

The registrant's report should contain (1) a stated goal of the study and (2) sufficient information on the test protocol (compound purity and type of compound used, complete characterization of soils, dose-level and method used) and the analytical protocol (description of methods used for quantitative and qualitative analyses and reports on the quality control procedures used to ensure the validity of the study).

Types of information that the registrant should include in the report are listed in Appendices 2 and 3.

III. THE EVALUATION PROCESS

A. Determine the Need for the Study

The reviewer should initially determine whether the study is required under 40 CFR §158.130. Normally, the study is required to support registratrion of each active ingredient of an end-use product intended for domestic outdoor use, greenhouse use, terrestrial noncrop and crop use, and forestry use. Such data are also required to support each application for registration of a manufacturing-use product which may legally be used to make such an end-use product.

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* Aged residues are those degradation products formed in soil after the test chemical has been aged 30 days under aerobic conditions.

B. Read the Report

Reports of soil column leaching studies are first reviewed to determine if the following information is present:

° Is the compound purity, type of compound used and site(s) of radiolabeling (if used) specified? If radioisotopic techniques are used, the test should be conducted individually with the analytical grade for each active ingredient in the product. Complex molecules must be labeled in appropriate sites to allow each major component of the molecule to be monitored. If non-radioisotopic analytical techniques were used, the test should be conducted with the technical or purer grade of each active ingredient in the product.

° Were four different textured soils used? If only one soil type was used, is the pesticide use limited to that soil only? Did one of the soils used have an organic matter content less than or equal to one percent (sand or sandy loam, for example)? Was one of the soils the same as that used in the aerobic soil metabolism testing? For the testing of aged residues, was the soil used the same as that used in the aerobic soil metabolism study?

° Is complete characterization of soils included [pH, moisture capacity, percent organic matter, bulk density, cation exchange capacity, and textural composition (percent sand, silt and clay) and textural class]?

° Was the amount of test substance added to the soil equivalent to the highest recommended label rate for one application of the active ingredient? Is the treatment rate and method of treatment of the soil described? Is the treatment representative of the use rate?

° Are the methods which were used for quantitative and qualitative analyses described?

° Is a material balance reported?

The reviewer should determine if there are data gaps within the study. Failure to furnish all this information may result in rejection of the report. In cases where needed information is missing, the study report should be returned without review but with a detailed list of the deficiencies.

C. Prepare the Data Evaluation Record (DER)

After the reviewer has determined there are no data gaps which would cause the report to be rejected, the reviewer prepares

a DER according to the Standard Format for Preparation of Environmental Fate Reviews.

1. Write the Technical Evaluation

The reviewer should use Appendices 2 and 3 as aids in this process. The technical evaluation should be prepared with the following points in mind:

a. The test protocol should provide adequate information as to how and under what conditions the study was conducted. Consult Appendix 2.

b. The analytical protocol should provide information on sensitivity and specificity of the analytical method(s) used and indicate how the results were determined. Consult Appendix 3.

c. The material balance aids in determining the validity of the study. Does the report account for all or the major portion (90-95%) of the test chemical applied to the soil? If not, is a rationale presented to explain why not? Does the report account for an excess greater than 105-115% of the amount of chemical applied?

d. Are the quality control measures taken to ensure the integrity of the test described? Were logbooks and record-keeping procedures maintained? Were quality procedures maintained during sampling, storage, and analysis of soil samples? Were good laboratory practices followed? Was the soil used in the aged test maintained in such a manner that viable microbial populations were present?

2. Determine Study Acceptability

Were the stated goals of the study appropriate and clearly defined? Was the study conducted in a scientifically sound manner to accomplish those goals? If so, the reviewer then makes a determination as to the acceptability of the study and considers whether the study, either as it stands alone or in light of other studies (combined testing, surrogate studies, or waivers), supports the requested registration action.

From the information presented, can it be concluded as to whether unaged residues (parent compound) and the degradation products (aged residues) are mobile in soil and thereby have potential to contaminate groundwater? If residues reach surface water, will they associate with the soil or remain in the water phase?

The results of the test should provide an estimate of the mobility of the test material and answer the questions:

° Is the test chemical mobile in soil under the conditions of the test?

° Are soil degradates mobile in soil under the conditions of the test?

° Can the mobility of the test material or its degradates be predicted in the soil under field conditions?

If the study is deficient, a detailed description of the deficiencies and recommendations on how to rectify the deficiencies is prepared and included in the DER.

3. Determine the Need for Deferral/Referral to Other HED Branches

If the reviewer concludes either that (1) the test chemical or its degradates has a potential for groundwater contamination, or (2) there is a potential for dispersal in the aquatic environment, then the Toxicology and/or Ecological Effects Branches are notified.

4. Make Regulatory Determination

Based on the technical evaluation, the reviewer determines whether the study satisfies the data requirement for a mobility study.

A reliable prediction of the potential for ground water contamination is made as the reviewer considers the results of the study in light of the results of other environmental fate studies (hydrolysis, photodegradation, soil metabolism, other mobility studies, field dissipation). Results of other studies (physical chemical data such as vapor pressure or octanol/water partition coefficients, combined testing, surrogate studies) or waivers can also be considered here.

Factors that increase hydraulic conductivity will increase percolation and the potential for pesticide leaching.[3] Coarse textured or well-aggregated soil with high proportions of large pores should be fairly permeable whereas infiltration will be restricted in clay-rich and compacted soils.[3]

In addition to bulk, density, and texture of soils, other characteristics affect the downward movement of pesticides in soil. Adsorption of pesticides to soil is the major factor influencing the movement of the pesticide.[3] A very water soluble compound will not leach if it is irreversible adsorbed and compounds which are very insoluble in water will leach if they are not restricted by adsorption.[4] Soil characteristics which influence adsorption are soil organic matter, amount and type of clay present, field moisture capacity, surface area, soil pH, and cation exchange capacity (CEC).[2, 3, 15, 17]

APPENDIX 1

General Theory

The movement of a pesticide through soil bears on its potential to reach adjacent soil or ground water. Leaching of a pesticide in soil depends on water movement.[3] In some cases, herbicide persistence beyond a normal cropping season is reduced by higher amounts of natural or artificially applied water.[4] In part, this can be attributed to dissipation of the herbicide into lower soil horizons.

Two general processes predominate in such movement, (1) diffusion and (2) mass transfer[2] (Note: Factors influencing movement, e.g., soil characteristics, will be discussed later.). Diffusion is the process by which the pesticide is transported as a result of random molecular motions caused by their thermal energy.[5] Mass transfer (flow) occurs as a result of external forces[5] acting on the pesticide.

Hamaker[6] noted that leaching through soil is a complex phenomenon with at least four elements:

1. "Soil adsorption which determines the underlying pattern;

2. Porous flow and diffusion which produce a dispersion of the chemical;

3. Adsorption dynamics which introduce a factor of hysteresis; and

4. Water infiltration and evaporation which determine the amount of water movement and hence, the observed amount of movement of a chemical."

The theoretical aspects of pesticide transport by soil-water movement have been well described.[7, 8, 9, 10, 11] Generally, pesticides entering the soil are leached in a vertical direction in the soil zone of aeration above the water table[12] with some lateral movement due to diffusion and dispersion. (Lateral movement may occur when the pesticide reaches a profile zone of water saturation and from capillary action near the boundary between dry and wetted soils).[2] [Movement of pesticides at the soil surface may occur by water (run-off) from sheet erosion and wind erosion.]

An equation describing water flow through soil is Darcy's law[5] and is expressed as:

$$v' = -ki \qquad (1)$$

where v' is the volume of water crossing per unit area perpendicular to the flow per unit time, k is the proportionality constant referred to as the hydraulic conductivity, and i represents the driving force which is the hydraulic head gradient. The reviewer is referred to many fine sources available which discuss Darcy's law.[13, 14]

The rate of soil-water infiltration and the magnitude of k depends on the relative distribution of large vs. small soil pores, the presence of abruptly discontinuous soil layers, and the initial soil moisture content.[2] Water will move in the direction of low to high matrix potential, i.e., from wet to dry soil. This explains why water (and dissolved chemicals) can move to the soil surface when a moist soil is drying out.[2]

The distribution of dissolved organic chemicals in soil water, as a function of time and depth, can also be described by chromatographic theory.[3] Here, the two major components of such movement are mass transfer and diffussion. Soil adsorption is the mechanism which is responsible for the pattern of movement of chemicals through soil.[6] Hence, movement downward decreases as adsorption increases. The adsorption of the chemical on the soil causes the moving front of the chemical to lag behind the moving front of the solvent.[6] This lag distance is known as "retardation."

It is noted,[6] however, that this chromatographic pattern is effected by flow through a porous medium which acts both to disperse and retard the chemical ("hydrodynamic dispersion"). Some of the liquid moves a greater distance through a more restricted passage or moves more slowly through smaller passages than that portion taking a more direct path.[6] Other factors effecting the chromatographic pattern include (1) a "frictional" effect (slow release by soil particles) when the chemical cannot get off the soil (desorb) fast enough, and (2) in the field, evapotransporation effects[6] - as the soil dries, there is an upward movement of water and chemical.

The effect of soil water content on diffusion is more complex than mass flow and depends on whether the chemical diffuses mainly in the vapor or solution phase.[9, 10] Movement by diffusion in water will be hindered by increasing bulk density[3] of the soil.

APPENDIX 2

Section 163-1 in the Subdivision N Guidelines describes this study and gives a protocol for conducting it. Also, Section 160-5 describes general reporting and evaluation requirements that should be included.

A. Information To Be Included

1. Dates on which the study began and ended;

2. Name and address of the laboratory or institution performing the test;

3. Location where the test was performed;

4. Name of the principal investigators;

5. Signatures of each of the senior personnel responsible for the study;

6. Certification by the registrant that the report is a complete and unaltered copy of the report provided by the testing facility;

7. The report should identify the test substance and include the chemical name and purity of the active ingredient; molecular structure; manufacturer, and lot and sample number(s) of the test substance(s); and properties of the test substance(s) [including physical state and pH] if not reported elsewhere;

8. Description of the soil source and soil characteristics;

9. A detailed report in tabular form of the test data (Graphs can be included to expand on the data given in tabular form);

10. A complete discussion of the results of the study.

B. Detailed Discussion

1. The Test Substance

The chemical to be tested must be chemically pure. The use of radiolabeled compounds is preferred. Carbon-14 is usually used; ring labeling is preferred to side-chain labeling because the radioactivity is usually less easily removed from the central ring positions. If the molecule is complex and consists of moieties that are easily separated, then radiolabeling in more than one location of the compound may be necessary. In any case, the site of radiolabeling must be defined.

Use of radiolabeled chemicals rather than non-labeled ones allows: (1) the leaching process to be followed at a much lower concentration and (2) easier determination of mass (material) balance. If non-labeled compounds are used, the study must be conducted with the technical or purer grade of the active ingredient(s).

2. The Test Soil

The study should include, at a minimum, four soils, such as sand (agricultural), sandy loam, silt loam, clay, or clay-loam, each having a pH within the range of 4-8. However, if the pesticide is limited to use with one specific soil type, then only one soil may be used, but it should be representative of that specific soil type. At least one of the soils selected should have an organic matter content less than or equal to one percent (A sand or sandy loam soil is preferred.). One of the soils should be the soil used in the aerobic soil metabolism study. A field soil sample should be a subsample from the top layer of the field soil. The soil should be sifted through a 2 mm sieve.[19] Packed columns commonly use soil passing a 2-mm screen.[3] For the aged soil-pesticide test, the soil should be freshly taken from a typical use area or have been maintained in such a manner that it has viable microbial populations present at the time of initiation of the test. The soil should be stored in a clean, chemical-free environment. For the aging test, the pesticide is applied to the soil and incubated aerobically for 30 days before a subsample is taken and added to the top of the column. It is recommended that the incubation be done in a closed container and trapping solutions be used to trap any volatile degradation products formed during the incubation period. It should be aerated.

Information on the soil class, texture, pH, and percent organic matter is necessary to verify that the soil is representative of agricultural soils. If foreign soils are used, such data on soil class, textural classification, and crop use are needed to indicate its similarity to U.S. soils.

3. Test Procedures

a. Study Apparatus

The use of segmented columns (glass or metal) is convenient. The use of machined rings permits later separation and analysis of the individual segments.[3] The column diameter must be at least one inch.[20]

Numerous column methods have been reported.[2] However, the selection of the soil column method will depend on the specific needs of the investigator.

b. Preparation Of The Column

The soil column should be, at a minimum, 30 cm in height, consisting of the prepared soil described above. Two types of soil columns have been classified, "natural" and "handpacked."[18] The "natural" or undisturbed columns have been used rather infrequently. At least two methods for natural column retrieval have been used.[2] A metal column may be driven into the soil and the surrounding soil removed prior to careful removal of the column. Power drills have also been used to obtain the soil cores.[21] In either method, compaction of the core should be avoided.[2] A general problem with both undisturbed and packed columns is edge effects or "channel flow" (preferential solvent flow along the inner column wall). If it occurs, it can result in a somewhat greater apparent mobility of the added chemical than expected.[2]

In the preparation of "handpacked" columns, care must be exercised for uniform packing. Weighed, air-dried, soil is added slowly with column vibration. Soil bulk density should be measured and reported and should be the same for all columns of the same soil (One major weakness of using soil columns to study leaching is the possibility of nonreproducibile results, which can be caused by nonhomogenous packing.[3]). Review techniques on soil column packing are discussed by Weber and Peeper.[18]

The soil column should be pre-wetted and allowed to equilibrate.[20] The column can be eluded while either unsaturated (containing some airfilled voids) or saturated (total pore volume is filled with water). While an unsaturated column would be more typical of flow in the normal unsaturated zone of the upper soil profile[3] (except during heavy rainfall or irrigation), it has been shown that leaching under unsaturated conditions is less effective than under saturated conditions.[6] Therefore, conducting the study under saturated conditions (constant head) is preferred so that a worst case situation will be simulated.

5. The Treatment Rate

The amount of parent pesticide added should correspond to the highest recommended rate for a single application. In the unaged test, the unlabeled or radiolabeled parent pesticide is added uniformly to the top of the soil column via treated soil or in a minimum amount of solvent. In the aged test, a measured portion of the 30-day aged pesticide-soil mixture is placed on an untreated column where the untreated soil is the same as the aged soil. The soil surface should be covered after pesticide addition with a disc of glass-fiber filter paper, sintered glass, or glass wool to minimize disturbance of the soil and uniformily distribute water during leaching.

c. The Study Conditions

To simulate a worst-case, water-saturated condition, the column is eluted with a volume of water equal to 20 inches (50.8 cm) times the cross-sectional area of the column, preferably using 0.01-0.02 N calcium chloride solution.[20] During the test, the solution should be percolated through the column at a rate which maintains a constant head above the soil surface. The reviewer should recognize that this is not representative of field leaching conditions but when the final environmental exposure assessment is made, the conclusion concerning leaching will be tempered by the results of the field dissipation study.

Amounts of eluate used, effluent collected (after drainage has stopped), the 1/3 bar moisture content, and the infiltration rate (in/hr or cm/hr) are to be reported. If the pesticide photodegrades, the study should be done in the dark. If the pesticide is volatile, provision should be made to trap and analyze the volatiles.

If columns of a specific length are used which prevent eluate from percolating through the bottom of the column, then a tracer should be used in the study.[20] This will provide information on how far the water moved through the column in relation to how far the pesticide residues moved through the column.

d. Sample Collection

After leaching, the soil is removed from the column and is sectioned into five or more equal lengths by slicing the soil with a spatula. Each slice is analyzed to detect pesticide residues and their movement.[2] Analysis includes determination of (1) total residue content (parent plus degradation products), and (2) identity of residues. Care should be taken as the soil is extruded from non-segmented columns so that contamination is minimized and so that the column structure is maintained. The leachate solution is analyzed for total radioactive content and the radioactive compounds present are identified.

Soil samples should be analyzed as soon as possible after completion of the test. If samples are stored before analysis, it must be shown that the pesticide residues do not degrade under the storage conditions.

A distribution curve of the test substance and its products in the column should be determined by quantification of the test substance and its degradates in the soil segments and in the leachate.

Note: Currently, the Guidelines[1] state that for the soil column study, values of pesticide distribution relationships (K_d) should be reported for the test substance and its degradates using appropriate equations. The researcher should develop the values. At this time, however, the test will not be considered deficient if this relationship is not included in the test report since the K_d values provided by the equations vary by a factor of two or more.[20] The theoretical aspects of associating the pesticide distribution relationship and K_d have been reported.[2, 6]

APPENDIX 3

Analytical Data To Be Submitted by the Registrant

A. Analytical Procedures

1. Analytical methods

A full description of the analytical method(s) used in all steps of the analytical protocol must be submitted, including the following information:

° Name (and signature), title, organization, address, and telephone number of the person(s) responsible for the planning and supervision/monitoring and laboratory procedures/analyses;

° Analytical method(s) title/designation, date;

° Source of analytical method(s);

° Principles of the analytical procedure;

° The analytical method(s) detailing in step-wise fashion the procedures (extraction, clean-up, determination, calculation of the magnitude of the residue);

° Reagents or procedural steps requiring special precautions (to avoid safety or health hazards, explain);

° Identification of the chemical species determined;

° Modifications, if any, of the analytical methods(s);

° Extraction efficiency;

° Instrumentation [make/model, type/specificity of detectors, column(s) packing materials, size, gas carrier, flow rates, temperatures, limit of detection and sensitivity, calibration procedures, etc];

° Interference(s), if any;

° Confirmatory techniques (e.g., other column packings, detectors, etc.);

° Date(s) samples taken, extracted and analyzed;

- Sample identification (coding and labeling information);
- Residue results (raw data, laboratory worksheets, step-wise calculation of residue levels, dilution factors, peak heights/areas, method correction factors applied (e.g., storage stability and method validation recovery values, standard curve(s) used, ppm found of "total" residues and of individual components if of special concern, range of residue values, representative chromatograms, spectra of control and treated samples);
- Statistical treatments (of raw data);
- Other (any and all additional information the registrant/researcher considers appropriate and relevant to provide a complete and thorough description of residue analytical methodology and means of calculating the residue results).

B. Method Validation

A full description of the method recovery validation procedures must be submitted and must include information on the following: the recovery level(s) of the test compounds from the soil (substrate) at various fortification level(s) using the residue analytical methodology; a validated sensitivity level; results of the study and any statistical tests applied; a step-wise presentation of the procedure for calculating percent recovery from the raw data; all the data/information necessary to idependently verify the results; summary of the data results; and conclusions drawn from the data results.

C. Quality Assurance

A complete description of the measures taken to ensure the integrity of the test and analytical protocols should include information on the following: log books and/or record-keeping procedures, representative instrument printouts (chromatograms, spectra, etc.), sample coding, use of replicate samples and control blanks, use of written and validated analytical methodology for residue analyses, including modification(s) made, skilled laboratory personnel, well-equipped laboratory facility, minimal contamination, calibration and maintenance of instruments; and good laboratory practices in handling the test substance(s).

D. Residue Analyses

Reported results should include:

1. Total Soil Residues (Pre-Extraction)

When ^{14}C labeled parent compound is used, the subsamples of each soil slice will be combusted and $^{14}CO_2$ formed will be

trapped in appropriate solvents.

2. Extractable Soil Residues

Soil is extracted with appropriate solvents, filtered and reextracted if necessary. Exhaustive extraction methods are sometimes necessary when residues are not extracted by gentler means. The reviewer should determine that an appropriate extracting solvent system was used in the study.

3. Non-Extractable Residues (Post-Extraction)

The post-extracted soil is combusted in an oxidizer and the CO_2 formed is trapped in appropriate solvent.

4. Total Leachate Residue

Aliquots of the leachate are analyzed for presence of parent compound and degradation products.

These residue totals make up the material balance. The material balance summed should equal 100% of the amount of the test chemical applied. Thus, the material balance is a factor in determining the validity of the study. Studies wherein the material balance does not account for a large percentage (90-95%) or accounts for greater than 105% to 115% of the amount of test chemical applied may be invalid and not useful in satisfying the data requirement.

5. Identification of Metabolites

Residues occurring at a level of 0.01 ppm or greater at normal field application rates under the label treatment schedule should be identified when feasible. Thin-layer chromatography (TLC) of extracted residues with co-chromatography of known standards is adequate for qualitative identification. Autoradiography of TLC plates provides a record for locating any labeled degradation products. Gas chromatography coupled with mass spectroscopy (GC/MS) provides positive metabolite identification. Quantitative analysis can be either by LSC, LC, or GC. All analytical methods must be examined for their specificity, sensitivity and recovery.

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